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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,332	01/09/2001	Samuel I. Achilefu	MRD-66	5505

26875 7590 09/01/2004
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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1616

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/757,332

Applicant(s)

ACHILEFU ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004 and 21 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-12, 16, and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-12, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/1/04 & 7/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment file 7/1/04 wherein the claim status is as follows: claims 1-3, 13-15, and 18-20 are canceled and claim 4 is amended. In addition, the Examiner acknowledges the acceptable terminal disclaimer and RCE both filed on 7/1/04.

Note: Claims 4-12, 16, and 17 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENT

2. The Applicant's arguments filed 7/1/04 to the rejection of claims 4-12, 16, and 17 made by the Examiner under 35 USC 112 and/or double patenting have been fully considered and deemed persuasive for the reasons set forth below. Therefore, all outstanding rejections are hereby withdrawn.

I. The double patenting rejection over application number 09/981,206 is WITHDRAWN because Applicant has abandoned 09/981,206.

II. The double patenting rejections over 6,183,726 and 6,180,086 are WITHDRAWN because Applicant has filed an acceptable terminal disclaimer.

III. The 112 rejections are WITHDRAWN because Applicant has amended the claims to overcome the rejections.

NEW GROUNDS OF REJECTION (Double Patenting Rejections)

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 4-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-5 and 15 of U.S. Patent No. 6,733,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of performing a diagnostic procedure wherein an indole compound is utilized. The claims are obvious over one another because a skilled practitioner in the art would recognize that the patented indole compounds overlap those of the instant invention when R45 is alkoxy, polyalkoxyalkyl, polyhydroxyalkyl, polyhydroxyaryl, saccharides, aminoalkyl, cyano, nitro, halogen, peptides, CH₂(CH₂-O-CH₂)_c-CH₂-OH; (CH₂)_d-CO₂T, and CH₂-

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(CCH₂-O-CH₂)_e-CH₂-CO₂T; V₅ = single bond; W₅ and X₅ are CRcRd; and R₃₇ – R₄₃ = (CH₂)_f-NH₂ or CH₂-(CH₂-O-CH₂)_g-CH₂-NH₂.

5. Claims 4, 5, and 7-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 16, 18, 19, and 21 of copending Application No. 10/653,728. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of performing a diagnostic procedure wherein and indole compound is administered. The claims are obvious over one another because a skilled practitioner in the art would recognize that the indole compounds of 10/653,728 overlap those of the instant invention when R₄₅ is alkoxy, polyalkoxyalkyl, polyhydroxyalkyl, polyhydroxyaryl, saccharides, aminoalkyl, cyano, nitro, halogen, peptides, CH₂(CH₂-O-CH₂)_c-CH₂-OH; (CH₂)_d-CO₂T, and CH₂-(CCH₂-O-CH₂)_e-CH₂-CO₂T; V₅ = single bond; W₅ and X₅ are CRcRd; and R₃₇ – R₄₃ = (CH₂)_f-NH₂ or CH₂-(CH₂-O-CH₂)_g-CH₂-NH₂.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 4-12, 16 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 4-12, 16, and 17 of copending Application No. 09/757,333. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims

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are directed to a method of performing a diagnostic procedure wherein and indole compound is administered. The claims differ over one another because in 09/757,333, W3 and X3 are selected from CR1R2, O, NR3, S, and Se while W5 and X5 are CR1R2 in the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

COMMENTS/NOTES

7. It is duly noted that no prior art has been cited against Applicant's claims. However, Applicant must address and overcome the double patenting rejections above. The claims are allowable over the prior art of record for reasons of record in the office action mailed 4/14/04.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
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August 30, 2004